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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/836,602 | 04/18/2001 | Axel R. Zander | 35-204 | 8963 |

7590 06/19/2002

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EXAMINER

LEFFERS JR, GERALD G

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1636 | (0 |

DATE MAILED: 06/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-----------------|-----------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/836,602 | ZANDER, AXEL R. |
| | Examiner | Art Unit |
| | Gerald Leffers | 1636 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on ____.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-23,26-29 and 31-34 is/are pending in the application.
 4a) Of the above claim(s) 1-23,26-29 and 31-34 is/are withdrawn from consideration.
 5) Claim(s) ____ is/are allowed. *Approved*
 6) Claim(s) ____ is/are rejected.
 7) Claim(s) ____ is/are objected to.
 8) Claim(s) 1-23,26-29,31-34 *Approved* are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 11) The proposed drawing correction filed on ____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) The translation of the foreign language provisional application has been received.
 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). ____.
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) Other:

DETAILED ACTION

Receipt is acknowledged of an amendment, filed 4/18/01 as Paper No. 3, in which claims were cancelled (claims 24, 25 and 30) and in which several claims were amended (claims 3-5, 9, 12-13, 16-20, 22-23, 26-28, 31-32). Claims 1-23, 26-29, 31-34 are pending in this application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-11, drawn to transduced host cells and gene transfer vectors comprising a nucleic acid encoding a CD34 surface marker, classified in class 435, subclasses 320.1, 252.3, 325.
- II. Claims 12-23, 26, 29, 33-34, drawn to kits and methods for detecting a genetically modified cell and for in vitro transduction of cells, classified in class 435, subclasses 7.1, 320.1, 455.
- III. Claims 27-28, 31-32, drawn to compositions and methods for gene therapy (in vivo or ex vivo), classified in class 514, subclass 44; class 424, subclass 93.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Group I and Groups II-III are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

product (MPEP § 806.05(h)). In the instant case the vectors and transduced cells can be used in the distinct methods of Groups II and III.

Inventions of Groups II-III are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The methods of Groups II-III comprise steps that are not required for or present in the methods of the other group: assaying transduced cells for the presence of a CD34 cell-surface marker (Group II) and administration of a gene therapy composition to a subject (Group III). The end results of the different methods are different: detection or sorting of cells comprising a CD34 cell-surface marker (Group II) and therapeutic treatment of a subject with a gene therapy composition (Group III). Thus, the operation, function and effects of the different methods and compositions from the different groups are different and distinct from each other. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

A telephone call was made to B.J. Sadoff on 11/26/01 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gerald G. Leffers Jr.
Gerald G Leffers Jr.
Examiner
Art Unit 1636

ggl
June 12, 2002